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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,919	12/06/2001	C. Frank Bennett	RTS-0256	7597

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,919	BENNETT ET AL.	
	Examiner	Art Unit	
	J. Douglas Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-6-2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, and also SEQ ID NO: 21, in the reply filed on April 12, 2004 is acknowledged.

SEQ ID NOS: 10-20, 22-28, 30-56, 58, 59, 61, 62, 66, 67, 69, 70, 73-76, 79, and 81-87, of claim 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 12, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to antisense compounds that target Ship-1, or its active sites, or said compounds internucleoside, sugar, nucleobase, and 2' modifications, chimeras, or compositions comprising said compounds and pharmaceutically acceptable diluents thereof.

Applicants are not considered to be in possession of the genus of any antisense molecule targeting any Ship-1 molecule. At the outset it is noted that the rejected claims do not recite any sequence identifier (SEQ ID NO), and the specification does not define Ship-1 as being limited to any one particular sequence. Thus, Ship-1 is thus considered to be defined and claimed by its function (Ship 1-like function) rather than by any particular structure. Accordingly such language embraces any sequence of any Ship-1 including any isoform or allele known or yet to be discovered from any species, or any such molecule with analogous Ship-1 like activity, or any variant that is within reasonable similarity from this family of proteins that retain Ship-1 function.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, and any combination thereof.

In this case, the claims are broadly drawn to any antisense compound targeting any Ship-1 that falls within the breadth discussed above. In contrast, the specification discloses only antisense sequences targeted to a single Ship-1 sequence (SEQ ID NO: 3). This is not considered

to provide support for possession of the genus of any antisense compound targeted to any Ship-1 molecule, because one could not immediately envision the genus of any Ship-1 from the disclosure of only one sequence of Ship-1, particularly in the absence of any teaching by way of structure what it is that actually confers Ship-1 like function. Since one of skill must necessarily know the sequence of a gene in order to design antisense inhibitors for that gene, and since applicants have only described the Ship-1 sequence of SEQ ID NO: 3, the genus of any antisense molecule targeted to any Ship-1 is not immediately envisioned because A) the genus of any antisense molecules with Ship-1 like activity is large, as discussed above, and B) the genus is expected to be vary across alleles and homologs from different species. One Ship-1 sequence is not considered to provide adequate support for a genus of any antisense molecules targeted to any Ship-1 molecule, particularly when that genus is both large and varied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 11, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohrschneider *et al.* (WO 97/10252, applicants IDS).

The invention of the above claims is drawn to antisense compounds 8 to 50 nucleobases long that target Ship-1, or said compounds that target the active site of Ship-1, comprising

internucleoside modifications including phosphorothioate modifications, or compositions comprising said compounds and pharmaceutically acceptable diluents thereof.

Rohrschneider teach antisense compounds at least 11 nucleobases long that target Ship-1, wherein said compounds target the active site of Ship-1, and comprise internucleoside modifications including phosphorothioate modifications, and compositions comprising said compounds and pharmaceutically acceptable diluents thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohrschneider *et al.* (WO 97/10252, applicants IDS), in view of Ware *et al.* (Blood 1996,

88:2833-40, AL in applicants' IDS), Taylor et al. (Drug Disc. Today, 1999. 4(12)562-567) and Baracchini et al. (U. S. Patent Number 5,801,154).

The invention of the above claims is drawn to antisense compounds 8 to 50 nucleobases long that target Ship-1, or said compounds comprising internucleoside, nucleobase, and 2' modifications, chimeras, or compositions comprising said compounds and pharmaceutically acceptable diluents thereof.

Rohrschneider et al. teach antisense compounds that target Ship-1. Furthermore, Rohrschneider et al. teach antisense compounds comprising phosphorothioate and other modifications or compositions comprising said compounds and pharmaceutically acceptable diluents thereof. Rohrschneider *et al.* do not teach antisense sequences comprising specific nucleobase, and 2' modifications, chimeras.

Ware et al. teach the cDNA sequence encoding Ship-1 of applicants disclosed SEQ ID NO:3.

Taylor et al. teach the inhibition of expression of any protein using a known cDNA sequence to generate antisense oligos that target and inhibit the expression of that protein, and also teach that with software analysis and high affinity oligos, one needs to screen only 3-6 oligos to find one that inhibits its target 66-95% (p. 565).

Baracchini et al. teaches modifications of antisense compounds comprising sugar, nucleobase, 2' modifications, chimeras, and compositions comprising said compounds and pharmaceutically acceptable diluents thereof. Baracchini et al. also teach targeting specific regions of a gene including the 5'-untranslated, start codon, coding, stop codon, or 3'-

untranslated regions, and demonstrate the methods necessary to screen for successful gene inhibition.

It would have been obvious to one of ordinary skill in the art to use the Ship-1 specific antisense sequences of Rohrschneider *et al.*, and incorporate into them the specific length requirements and modifications as taught by Taylor *et al.* and Baracchini et al. for inhibition of Ship-1 expression. One would have been motivated to create such compounds because Rohrschneider et al. expressly teach phosphorothioate-modified antisense compounds directed to the Ship-1 target, and because Baracchini *et al.* teach the same antisense oligo modifications as instantly claimed, and indicate that modifications as taught by Rohrschneider and Baracchini provide for an antisense compound's increased cellular uptake, target affinity and resistance to degradation. Finally, one would have a reasonable expectation of success given that Ware teaches the cDNA sequence of Ship-1 (applicants' SEQ ID NO:3) for designing antisense oligos against any portion of the gene, and further because Taylor teaches that with software analysis and high affinity oligos, one needs to screen only 3-6 oligos to find one that inhibits its target 66-95%, and finally since Baracchini et al. teach making modified antisense compounds targeted to distinct regions of a target gene and methods of screening for successful gene inhibition, the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD

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